

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 19

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UNITED STATES PATENT AND TRADEMARK OFFICE

DEC 31 2003

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

**PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte GORAN MARNFELDT
and STEPHEN THEOBALD

Appeal No. 2003-1629
Application No. 09/297,899

HEARD: December 9, 2003

Before COHEN, STAAB, and McQUADE, Administrative Patent Judges.
STAAB, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's final rejection of claims 1-16, all the claims currently pending in the application. Subsequent to the final rejection, appellants submitted a proposed amendment (Paper No. 9) to overcome the rejection of the appealed claims under 35 U.S.C. § 112, second paragraph, which amendment was approved for entry by the examiner (see Paper No. 10). As a result, only the rejection of claims 1-5

and 7-16 based on prior art remain before us for review, with claim 6 presumably being allowable if rewritten in independent form.¹

Appellants' invention pertains to an inhaler for administering medicament by inhalation, the inhaler including an electronic dose counting unit for counting each dose of medicament and displaying information providing an indication as to the usage of the inhaler. A further understanding of the invention can be derived from a reading of representative claim 1, which is reproduced below with drawing figures and reference numerals added in brackets:

1. An inhaler for administering medicament by inhalation, comprising:

an inhalation channel [24 in Fig. 3];

a rotatable dosing unit [16 in Fig. 3] which includes at least one dosing element [18] for providing a dose of medicament to the inhalation channel; and

a dose counting unit [42 in Fig. 3] which comprises an electronic display [57 in Fig. 9(f)] that displays usage of said inhaler, an electrical circuit [56] for counting each dose of medicament provided to the inhalation channel and driving the display so as to provide an indication as to said usage of the inhaler, the electrical circuit including at least one switch [62, 62b] which comprises a contact element [62] that is movable between a first open position and a second closed position when a dose of medicament is provided to the

¹The final rejection (Paper No. 6) did not reject dependent claim 6 on prior art and indicated on page 9 that claim 6 would be allowable if amended or rewritten to overcome the 35 U.S.C. § 112, second paragraph, rejection.

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inhalation channel, and a rotatable member [45] connected to the dosing unit so as to be rotatable therewith, the rotatable member including at least one cam surface [51] which includes at least one cam [51a], each cam on each cam surface being configured, on rotation of the dosing unit to provide a dose of medicament to the inhalation channel, to be in physical contact with said contact element and cause movement of the contact element of said at least one switch between said first open position and said second closed position.

The references relied upon by the examiner as evidence of obviousness are:

Wolf et al. (Wolf)	5,505,195	Apr. 9, 1996
Ambrosio et al. (Ambrosio)	5,687,710	Nov. 18, 1997

Claims 1-5 and 7-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ambrosio in view of Wolf.

Discussion

A rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967). In the present case, we believe the examiner has failed to advance a sufficient factual basis to support his

conclusion that it would have been obvious to one of ordinary skill in the art to modify the inhaler disclosed by Ambrosio in a manner that would result in the subject matter of the appealed claims.

Ambrosio is directed, in pertinent part, to an inhaler for powdered medications comprising a mechanism for counting the number of doses administered. As explained at column 2, line 66, through column 3, line 16 (with drawing figures and reference numerals added in brackets):

In accordance with one aspect of the present invention, a counter for a powder dispenser includes a continuous counter ring [590 in Figures 4 and 67-70] having counting indicia thereon; an intermittent counter ring [620 in Figures 4 and 71-74] adjacent to the continuous counter ring, the intermittent counter ring having counting indicia thereon; display means [330 in Figure 4] through which one of the counting indicia from the continuous counter ring and one of the counting indicia from the intermittent counter ring are displayed to indicate a count corresponding to a number of doses of powdered material that have been dispensed or remain to be dispensed; and actuating means [pawl assembly 640 in Figures 4 and 75-77 connected to rotatable base 200] for rotating the continuous counter ring one increment each time that a dose of the powdered material is dispensed to display another one of the counting indicia of the continuous counter ring, and for rotating the intermittent counter ring one increment for a predetermined number of rotational increments of the continuous counter ring to display another one of the counting indicia of the intermittent counter ring.

Of particular importance in the present case is the following statement of Ambrosio regarding the possibility of utilizing an

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electrical counter as an alternative to the specifically disclosed mechanical counters:

Many types of mechanical and electrical counters are useful. *A digital electronic counter can be disposed within the base or other areas of the device, and will require electrically conductive contacts which complete a circuit at some point in the dose loading operation; the characteristics of the required battery will be a factor in establishing a shelf life for the device. Presently preferred is counter mechanism 580, a decrementing mechanical counter that indicates the number of doses remaining to be dispensed. [Column 25, lines 23-32; emphasis added.]*

According to the examiner (answer, pages 3-4), one of ordinary skill in the art would have derived from the above noted disclosure of Ambrosio regarding an electronic counter that the electronic circuit for counting each dose

would . . . be understood to include a conventional switch arrangement comprised of contact elements arranged to have a first open position and a second closed position, when a dose of medicament is provided to the channel, a rotatable member (590) connected to the dosing unit, which is a cam (a rotating or sliding piece in a mechanical linkage) having a camming surface (the surface of the various gear teeth 602/604/606), configured to rotate the dosing unit to provide a dose of medicament to the inhalation channel, where the cam will be in physical contact with a contact element and is capable of causing movement of a contact element respective of the at least one switch from an open position to a closed position (see figs. 67-82 & 93-104) or where the contact element is locate-able within the path of travel of the cam for first and second position displacement, but Ambrosio does not disclose the display being "electronic" and connected to the electric circuit and the electric counting mechanism as set forth by Appellant.

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The examiner turns to Wolf for its disclosure of an inhaler having an electronic counter comprising LED display 1035. The examiner concludes that it would have been obvious to one of ordinary skill in the art in view of Wolf's teaching to provide Ambrosio with an electronic display to thereby arrive at the claimed subject matter.

Our main difficulty with the examiner's rejection centers on the examiner's liberal interpretation of what one of ordinary skill in the art would have derived from the rather meager disclosure of Ambrosio regarding the use of an electronic counter as an alternative to the specifically described mechanical counters. Like appellants, we are at a loss to find any disclosure in Ambrosio that amounts to a showing of a dose counting unit that comprises a contact element that is movable between open and closed positions when a dose of medicament is provided, and a rotatable member connected to a dosing unit so as to be rotatable therewith, wherein the rotatable member includes a cam configured to be in physical contact with the contact element and cause it to move between open and closed positions. The examiner's attempt (answer, pages 3, 4 and 9) to bridge the gaps between Ambrosio's broad disclosure and the specifics of the electronic counter set forth in the claims by theorizing as to what a "conventional" switch

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arrangement might comprise, pondering what constitutes the level of ordinary skill in the art, and/or speculating as to what one of ordinary skill in the art may or may not have inferred from the disclosure of Ambrosio does not suffice. Simply put, Ambrosio does not disclose, suggest or infer that the alternative electronic dose counter embodiment broadly described at column 25, lines 19-32 includes the particulars of the claimed dose counter.

In addition, the examiner's attempt to find correspondence between portions of Ambrosio's mechanical counter and certain elements of the claimed dose counter is not well taken. For example, contrary to that which is implied by the examiner in the paragraph spanning pages 3 and 4 of the answer, the continuous counter ring 590 does not correspond to appellants' claimed rotatable member having at least one cam. Moreover, the ratchet teeth 602/604/606 of Ambrosio's counter ring 590 do not function as camming surfaces to contact and actuate contact elements.

Wolf does not make up for the above noted deficiencies of Ambrosio. In Wolf, the electronic counter circuit includes reed switches (435, 436 in Figs. 4a, 4b and 5) that are closed when positioned in proximity of a magnet (122 in Figs. 1 and 2d) to cause the counter circuit to record when a dosage of medicament is released. As such, there is no physical contact between a contact

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switch and a camming means to close a switch, as called for in independent claim 1, or contact located within the path of travel of a cam so as to displace the contact between open and closed positions, as called for in independent claim 16.

In light of the foregoing, we agree with appellants' argument to the effect that one of ordinary skill in the art would not have been led to provide an electronic dose counting unit in Ambrosio that corresponds to the electronic dose counting unit called for in appellants' claims. It follows that we shall not sustain the examiner's rejection of claims 1-5 and 7-16 as being unpatentable over Ambrosio in view of Wolf.

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The decision of the examiner is reversed.

REVERSED

IRWIN CHARLES COHEN
Administrative Patent Judge

LAWRENCE J. STAAB
Administrative Patent Judge

JOHN P. McQUADE
Administrative Patent Judge

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